## REMARKS

No claim has been added or canceled in this response. Claim 1 has been amended to relate to porous bodies comprising pores from complete sublimation of solid ice from the water phase of the emulsion, and from the complete sublimation of the oil phase of the emulsion. Support for this amendment can be found at least at page 10, lines 4-7 of the specification as filed. Claim 1 has also been amended to recite that the oil phase of the emulsion is volatile. Support for this amendment can be found at least at page 10, line 26 through page 11, line 3 of the specification as filed, which describes volatile organic solvents. Applicants respectfully submit that the amendments add no new matter.

With entry of the amendment, claims 1, 3-9 and 21 will be pending in the application.

**Rejections under 35 U.S.C. § 103**

Claims 1, 3, 5-9 and 21 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Gregory in view of U.S. Patent No. 5,660,857 to Haynes *et al.* ("Haynes"). The Examiner states that "(t)hough Gregory et al does not explicitly state the lattice being formed from oil-in-water emulsion and specify the porous bodies having two types of pores as recited in instant claim 1, however, . . . Haynes et al further discloses a process for preparing a composite comprising preparing an oil-in-water-emulsion followed by freeze drying the emulsion (col. 2, lines 40-42) to form a sponge (col. 2, lines 30-31). The oil phase is used for dissolving oestradiol hydrophobic drug (col. 4, lines 34-36; col. 2, lines 50-51)." Attachment to Advisory Action at page 4, emphasis in original.

Applicants respectfully traverse the rejection and submit that a *prima facie* case of obviousness has not been established.

Amended claim 1 is reproduced below:

> 1. Porous bodies comprising a three dimensional open cell oil-in-water emulsion-formed lattice which porous bodies are water soluble such that hydrophobic materials contained within the lattice are dispersed when the porous bodies are exposed to an aqueous medium, the porous bodies containing
>
> (a) 10 to 95% by weight of a water soluble polymeric material and
>
> (b) 5 to 90% by weight of a surfactant,
>
> said porous bodies having an intrusion volume as measured by mercury porosimetry of at least about 3 ml/g; having hydrophobic material incorporated into the polymeric lattice; and comprising two types of pores:
>
> (1) from complete sublimation of solid ice from the water phase of the emulsion, and
>
> (2) from the complete sublimation of the oil phase of the emulsion;

with the proviso that said porous bodies are not spherical beads having an average bead diameter of 0.2 to 5mm;
wherein the oil of the oil phase of the emulsion is a volatile oil; and
wherein the bodies are in the form of powders, beads or moulded bodies.

Gregory discloses a pharmaceutical (or other chemical) dosage form that is rapidly disintegrable. This is achieved by providing a "shaped" article comprising an open matrix network of water-soluble or water-dispersible polymeric carrier material carrying a chemical (see, for example, col. 1, lines 21-24, 34-36, 44-49, 54-57 and 58-64). It is said that the open matrix network is similar in structure to a solid foam (col. 2, lines 48-49) and that rapid disintegration of said matrix results in the rapid release of any pharmaceutical or other chemical carried by the matrix (col. 2, lines 58-60). The dosage form is prepared by freeze-drying a composition comprising the pharmaceutical and a solution of the carrier material in solvent, and optionally other ingredients such as a surfactant (col. 3, line 57 to col. 4, line 7).

Applicants respectfully disagree with the Examiner's statement that one of skill in the art, when viewing Gregory, would have been motivated to include a co-solvent that would lead to formation of an emulsion when mixed with the aqueous solution of the polymeric carrier material. While Gregory does mention the possible use of a co-solvent, it is stated that that "(t)he solvent is preferably water but it may contain a co-solvent (such as an alcohol e.g. tert-butyl alcohol) to improve the solubility of the chemical" (col. 3, line 68 to col. 4, line 2). The only co-solvents mentioned are water-miscible alcohols, which would not form an emulsion when added to the aqueous polymer solution.

Additionally, as described in the previous response, when considering Gregory as a whole, one does not find any guidance relating to porous bodies having an oil-in-water emulsion-formed lattice. Gregory discloses that "(t)he sublimation is preferably carried out by freeze drying a composition comprising the chemical (e.g. pharmaceutical substance) and **a solution** of the carrier material in a solvent." (Col. 3, lines 63-66.) This reference to a solution does not suggest the formation of an emulsion. Furthermore, the Examples of Gregory teach either dissolving the active agent in water or a water-miscible solvent, or dispersion or suspension of an active agent in an aqueous solution. Accordingly, Gregory does not disclose or remotely suggest an oil-in-water emulsion-formed lattice, or a porous body having pores that are "from the complete sublimation of the oil phase of the emulsion" as described in claim 1.

In response to similar arguments made in the previous response, the Examiner alleges that "a preferred embodiment such as an example is not controlling. Rather, all disclosures 'including unpreferred embodiments' must be considered." Attachment to Advisory Action at

page 4. Applicants respectfully submit that Gregory does not disclose or provide any guidance to one skilled in the art regarding an oil-in-water emulsion even as an unpreferred embodiment. The word "emulsion" does not appear in the reference at all. Furthermore, Gregory uses the term "co-solvent" to describe the additional solvent that may be added to improve the solubility of the chemical. Applicants submit herewith as Exhibit A a definition of the term "co-solvent" from the Encyclopedia of Pharmaceutical Technology. This reference defines cosolvents as "**water-miscible** organic solvents that are used in liquid drug formulations to increase the solubility of poorly water-soluble substances or to enhance the chemical stability of a drug." Accordingly, contrary to the Examiner's assertion, one of skill in the art when viewing the term "co-solvent" would not have envisioned a water-immiscible solvent such as an oil.

Additionally, the statement "improve the solubility" in Gregory further suggests an embodiment in which a water-miscible solvent is added to the water to improve the solubility of the chemical in the water itself. An oil such as, for example, those described in Applicants' specification, would not "improve the solubility" of the chemical in the water phase. It would rather act as a solvent for the chemical itself (i.e., chemical in a non-aqueous phase), and then form an emulsion with the water.

In summary, Applicants submit that an oil-in-water emulsion is not disclosed or remotely suggested as an embodiment in Gregory. Accordingly, one of skill in the art at the time the invention was made, when viewing Gregory, would not have looked to Haynes or any other secondary reference for guidance as to the use of an oil-in-water emulsion.

Haynes discloses "a process for preparing a composite comprising an insoluble protein matrix and an oleaginous material, which is useful as a material for surgical dressings and biomedical implants, and as a cosmetic material for application to the skin." Haynes, Abstract. The composites of Haynes are prepared by mixing a protein, the oleaginous material, and water to form an emulsion of the oleaginous material in an aqueous dispersion of the protein, and subsequently drying the emulsion to remove the water only. The final product still contains the oleaginous material and is therefore actually a dry emulsion. Specifically, Haynes states that "a biopolymer matrix based on an insoluble protein can be formed with **significant quantities of an oleaginous material held within the matrix itself** (rather than physically entrapped within the pores of such a matrix), and that such a material exhibits a surprisingly non-oily or non-greasy appearance and feel." Haynes at col. 1, line 66 to col. 2, line 5 (emphasis added). Haynes also states that "the emulsion is frozen and then freeze dried, to form a sponge, the matrix of the sponge being formed of the insoluble protein/oleaginous material composite. In this embodiment, too, the oleaginous material may appear as discrete microscopic droplets

when surface of the sponge matrix is viewed." *Id.* at col. 2, lines 30-35. Finally, the Examples refer to a collagen/oil sponge, collagen/oil film, or collagen/oil microspheres. The formation of a dry emulsion, which when added to water would reform the original emulsion due to the continued presence of the oil, is quite different from the emulsion-formed porous bodies of claim 1 which would not reform the original emulsion upon addition to water.

First, given that the subject matter disclosed in Gregory and Haynes is rather divergent (e.g., soluble matrix of Gregory and insoluble protein matrix of Haynes), Applicants believe that it would have been unlikely that one of skill in the art at the time the present invention was made would have considered the disclosures of Gregory and Haynes as a logical combination. That is, given the disclosure of water soluble matrices in Gregory, it is unclear why one of skill in the art would look to combine it with a disclosure that relates to the formation of insoluble protein matrices.

Nevertheless, even if one of skill in the art were to have combined the teachings of Gregory with those of Haynes, the combination still fails to render claimed subject matter obvious. As described above, the oil remains present in the final product of Haynes. The Examiner has argued that "(t)hough Haynes et al recites that significant quantities of an oleaginous material held within matrix, however, that does not mean that during freeze drying step oil phase will not sublimate at least partially to form pores." Attachment to Advisory Action at page 5. Claim 1, as amended, relates to porous bodies that include pores "from the **complete** sublimation of the oil phase of the emulsion." As described above, Haynes discloses composite materials that have significant quantities of an oleaginous material held within the matrix. Accordingly, Applicants submit that Haynes does not disclose materials in which the oil phase has completely sublimed (i.e., significant quantities of oleaginous material remains within the matrix).

Haynes also does not disclose an oil phase of an emulsion wherein the oil is a volatile oil, as claimed. Rather, the oleaginous materials of Haynes are "a grease, a fat or a wax. . . . Suitable oils include mineral oils and vegetable oils." Haynes at Col. 2, ll. 50-55. One of skill in the art understands that such oils are non-volatile.

In summary, neither Gregory nor Haynes teaches or suggests porous bodies comprising a three dimensional open cell oil-in-water emulsion-formed lattice, comprising two types of pores: (1) from complete sublimation of solid ice from the water phase of the emulsion, and (2) from the complete sublimation of the oil phase of the emulsion, as claimed. For at least the reasons set forth above, Applicants submit that one of skill in the art would not have combined

the disclosure of Gregory with that of Haynes, and even if one had combined the references, one would not have arrived at the subject matter of claim 1.

Claims 3, 5-9 and 21 depend either directly or ultimately from claim 1 and accordingly are not obvious over Gregory in view of Haynes for at least the same and similar reasons. Applicants respectfully request reconsideration and withdrawal of the rejection.

Claims 1, 3-9 and 21 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Gregory in view Haynes, in further view of U.S. Patent No. 5,648,093 to Gole *et al.* ("Gole"), .U.S. Patent No. 5,502,082 to Unger *et al.* ("Unger"), and Japanese Patent Application No. JP 01011141 to Fujimoto *et al.* ("Fujimoto"). The Examiner concedes that "Gregory et al in view of Haynes et al do not teach the porous articles comprising cellulose material such as hydroxyethylcellulose or sodium salt of carboxymethylcellulose, the specific ratio between the polymer and a surfactant." Office Action at page 8.

Applicants respectfully submit that as discussed above, one of skill in the art, when viewing Gregory or Haynes alone or in combination, would not have arrived at the subject matter of the pending claims. For the same and similar reasons as those that have already been made of record, Applicants submit that none of Gole, Unger and Fujimoto remedies the deficiencies of Gregory and Haynes.

Gole discloses "a fast dissolving, solid dosage form defined by a matrix containing gelatin, pectin and/or soy fiber protein and one or more amino acids having from about 2 to 12 carbon atoms" (Gole, Abstract). Unger discloses a "cross-linked, highly porous body derived from a water-soluble, hydrogel polymer" (Unger, Abstract). Fujimoto discloses a "method of obtaining a porous material by freeze drying method using a hydrophilic polymer aqueous liquid" in which "freeze-drying is performed with addition of a surfactant to this aqueous liquid." None of the references teaches or suggests porous bodies comprising a three dimensional open cell oil-in-water emulsion-formed lattice, comprising two types of pores: (1) from complete sublimation of solid ice from the water phase of the emulsion, and (2) from the complete sublimation of the oil phase of the emulsion, as claimed.

Applicants respectfully request reconsideration and withdrawal of the rejection.

## CONCLUSION

In view of the foregoing, Applicants submit that the claims are in condition for allowance. Favorable consideration of the present application is therefore respectfully requested. If a conference call would be useful in resolving issues arising from the filing of this communication, please contact the undersigned at the below-noted number.

Respectfully submitted,

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